

# Notice of Allowability

Application No.

09/595,682

Applicant(s)

DANKS ET AL.

Examiner

Celine X Qian

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--  
claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included  
reewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS  
NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative  
the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

☒ This communication is responsive to the Amendment filed on 12/15/03.

☒ The allowed claim(s) is/are 12, 13, 22 and 26.

☒ The drawings filed on 16 June 2000 are accepted by the Examiner.

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some\* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the  
International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements  
noted below. Failure to timely comply will result in ABANDONMENT of this application.  
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF  
INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of  
Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of  
each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the  
attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

☐ Notice of References Cited (PTO-892)

☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_

☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material

5. ☐ Notice of Informal Patent Application (PTO-152)

6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_

7. ☒ Examiner's Amendment/Comment

8. ☐ Examiner's Statement of Reasons for Allowance

9. ☐ Other \_\_\_\_\_

Anne-Marie Falk

ANNE-MARIE FALK, PH.D.  
PRIMARY EXAMINER

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's representative Bridget Timona on 3/18/04.

The application has been amended as follows:

Claim 12 (currently amended): A method for sensitizing tumor cells to a chemotherapeutic prodrug APC or CPT-11 *in vitro* [capable of being cleaved by a carboxylesterase] comprising transfecting selected tumor cells with a composition comprising an isolated polynucleotide encoding a carboxylesterase [which cleaves a chemotherapeutic prodrug] wherein said carboxylesterase is operably linked to a promoter that directs expression of said carboxylesterase in said tumor cells, and wherein expression of the carboxylesterase renders the tumor cells more sensitive to the cytotoxic effect of said chemotherapeutic prodrug APC or CPT-11.

Claim 13 (currently amended): A method of inhibiting tumor cell growth *in vitro* comprising:

(A) sensitizing tumor cells in accordance with the method of claim 12; and

(B) contacting said sensitized tumor cells with said chemotherapeutic prodrug CPT-11 or APC so that tumor cell growth is inhibited.

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Claim 22 (currently amended): The method according to claim 12 wherein the carboxylesterase is selected from the group consisting of rabbit [polynucleotide] carboxylesterase and human intestinal [polynucleotide] carboxylesterase.

Claims 14, 18, 23-25, 27-29 are cancelled.

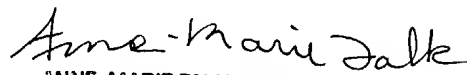
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777.

The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

  
ANNE-MARIE FALK, PH.D.  
PRIMARY EXAMINER